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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO:	CONFIRMATION NO.
09/808,898	03/15/2001	Bruce Bryan	LUME 48487	4894

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PIETRAGALLO, BOSICK & GORDON
ONE OXFORD CENTRE, 38TH FLOOR
301 GRANT STREET
PITTSBURGH, PA 15219-6404

EXAMINER	
LIU, SAMUEL W	
ART UNIT	PAPER NUMBER
1653	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/808,898	Applicant(s) BRYAN ET AL.	
	Examiner Samuel W Liu	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 MAY 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Preliminary amendment of Claims 19, 26, 40, 47, 53, 57, 70, 73 and 74 filed 25 May 2001 has been entered. The following Office action is applicable to the pending claims 1-77.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, 22, 38-50 and 57-58, drawn to an isolated polynucleotide, a vector and a host cell, are classified in class 536, subclass 23.1, class 435, subclasses 69.1, 320.1, 252.3 and 325^{+}.

II. Claims 14-21 and 51-56, drawn to an isolated green fluorescent protein (GFP) polypeptide Isolated and a composition comprising GFP protein, luciferase and substrate thereof, are classified in class 530, subclasses 350 and 412, class 514, subclass 2, class 435, subclass 69.7, and class 424, subclass 94.1.

III. Claims 23-28 and 30-35, drawn to a combination comprising a manufactured article and GFP polypeptide, a luciferase and substrate thereof, are classified in class 514, subclass 2, class 530, subclass 350, class 510, subclass 108, and class 800, subclass 295, and class 40, class 446, and class 442.

IV. Claims 23 and 27-29, drawn to a combination comprising a transgenic plant and GFP polypeptide, are classified in class 514, subclass 2, class 530, subclass 350, class 800, subclass 295.

V. Claims 36-37, drawn to an antibody, are classified in class 530, subclass 387.1.

VI. Claims 59-63, drawn to a biosensor comprising GFP protein and a modulator, are classified in class 514, subclass 2, class 702, subclass 19, class 435, subclass 72.1.

VII. Claims 64-69, drawn to a bioluminescence resonance energy transfer (BRET) system comprising GFP protein, a modulator, luciferase and substrate thereof, are classified in class 514, subclass 2, class 424, subclasses 9.1 and 94.1, and class 436, subclass 172.

VIII. Claims 70-74, drawn to a microelectronic device and a method of detecting and identifying analytes using the device thereof, are classified in class 73, and class 436, subclass 172.

IX. Claims 75-77, drawn to a transgenic animal, are classified in class 800, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and V are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention II is drawn to polypeptide and Invention V to an antibody while Invention I is drawn to a polynucleotide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

In addition, Invention I is directed to polynucleotides that is classified in class 536, subclass 23.1, and/or to a cell into which polynucleotides is transferred and a vector where the polynucleotide is bale to directing biosynthesis of the gene product, which process would have been searched in class 435 subclass 69.1. Invention V is directed to antibody that is classified in class 530, subclass 387.1. Thus, they acquire the different classification.

Inventions II (polypeptide) and Invention V (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Although antibody is belong to a types of polypeptide, antibody is glycosylated and its tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. Thus, the macromolecule of each invention would be expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use.

Inventions II (a GFP protein) and Invention VI (GFP-luciferase-GFP fusion protein) are also distinct from each other because of the materially different structures and different biological function, e.g. the fusion protein that contains luciferase enzyme catalyzes the substrate to yield yellow-emitting fluorescence whereas a green fluorescent protein (GFP) possesses no catalytic activity but is able to generate green-emitting fluorescence. Thus, the macromolecule of each invention would have been expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use. Invention I is unrelated to Inventions II, IV, IX, X , XI and XII. Inventions are unrelated if it can be shown that they are not disclosed

as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotide directs biosynthesis of mRNA and polypeptide, which mechanism is distinct from that of GFP or GFP fusion protein mediated bioluminescence.

Inventions I, II and V, which are directed to biomolecules, are patentably distinct from Invention IX, which is multicellular organism, one another because they are distinct composition, classified in different subclass and required different search.

Invention I is related to Inventions II, IV, VI, VII and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, mode of action of polynucleotide encoding GFP protein differs from the molecular mechanism in which GFP polypeptide involved, e.g., bioluminescence mechanism.

Invention III and invention II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, 1) the combination as claimed does not require the particulars of the subcombination as claimed because the combination (comprising GFP and manufacture articles) utility does not necessary depend on the utility of each separate article for patentability, and 2) the GFP has utility in other combination, e.g. GFP can be used in proteinchip for screening drug.

Invention IV and invention II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, 1) the combination as claimed does not require the particulars of the subcombination as claimed because the combination (comprising GFP and manufacture articles) utility does not necessary depend on the utility of each separate transgenic ornamental for patentability, and 2) the GFP has utility in other combination, e.g. GFP can be used in proteinchip for screening drug.

Invention VI and invention II, and Invention VII and invention II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as

claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, 1) the combination as claimed does not require the particulars of the subcombination as claimed because the combination (comprising GFP and manufacture articles) utility does not necessary depend on the utility of each separate modulator for patentability, and 2) the GFP has utility in other combination, e.g. GFP can be used in proteinchip for screening drug.

Invention VIII and invention II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, 1) the combination as claimed does not require the particulars of the subcombination as claimed because the combination (comprising GFP and manufacture articles) utility does not necessary depend on the utility of each separate photodetector for patentability, and 2) the GFP has utility in other combination, e.g. GFP can be used in proteinchip for screening drug.

Invention III and Inventions IV, VI, VII, VIII and IX are patentably distinct from one another because of the materially different structures of the compositions claimed. The composition of Invention III are different/distinct from that of Invention IV, VI, VII, VIII and IX, e.g., the transgenic ornamental plant is absent in Invention IV, and, modulator of Inventions VI and VII and array of Invention VIII are absent in Invention III. They would be expected to exhibit different chemical properties and are capable of separate manufacture or use.

Invention V is also unrelated to Inventions III, IV, VI, VII, VIII and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the combination functions differently from antibody (Invention V), the fusion protein (Invention VI), biosensor (invention VII), microelectronic device (Invention IX), transgenic organism (Inventions X and XI), the process of bioluminescence resonance (Invention VIII), and process of detecting analyte (Invention XII).

Invention V is unrelated to Inventions VII, VIII, IX, X, XI and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the mode of operation of antibody is distinct from that of the

composition of Invention V, or Invention IV, or Invention VI, or Invention VII, or Invention VIII, or Invention IX.

Additional Election Under 35 USC 121

Regardless of the elected group, applicant is required under 35 US 121 (1) to make the following elections with respect to patentably distinct inventions; and (2) to list all claims readable thereon including those subsequently added.

If Group I is elected, applicant is required under 35 US 121 (1) to elect one polynucleotide sequence from claim 41 because each polynucleotide is structurally distinct and directed to an independent invention as well as has different structure capable for different manufacturing and use.

If Group II is elected, applicant is required under 35 US 121 (1) to elect one organism for bioluminescence generation fro Claim 19, because each organism is patentably distinct one another.

If Group III is elected, applicant is required under 35 US 121 (1) to elect one article form claims 28 and 35 because each article has different structure, chemical components and capable for different manufacturing and use.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL
September 25, 2002

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER